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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,421	07/30/2001	Akira Suyama	01450/HG	6390

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FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,421	Applicant(s) SUYAMA, AKIRA	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>0506</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 24 February 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-5 and 8-10 have been cancelled. Claims 6, 7, and 11-15 are currently pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6, 7, and 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 6, 7, and 11-15 are rejected, based upon the new Interim Guidelines published in November 2005. Applicant is invited to view the following web site for the text of those guidelines:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

The method of the instant claims is directed to entering data (a nucleotide sequence) into a computer and extracting information from the sequence *in silico*. The claims do not produce a result which is concrete, tangible, and useful. The claims merely encompass combinations of groups of data, with no specific output that meets the concrete, tangible, and useful criteria. No specific output are set forth in the claims such that the steps of the method produce a result that is immediately concrete, tangible, and useful. The claims merely rearrange data elements of a nucleotide sequence within the confines of a computer. The claims must, as a whole, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention “transforms” and article or physical object to a different state or thing.

[*The claimed invention in the instant case does not transform any physical object or article*]

2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) [*The claimed invention in the instant application does not produce a concrete, tangible, and useful result*].

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula

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to a ... process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is “abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

Descriptive material can be characterized as either “functional descriptive material” or “nonfunctional descriptive material”. In this context, “functional descriptive material” consists of data structures and computer programs which impart functionality when employed as a computer component (The definition of “data structure” is “a physical or logical relationship among elements. Designed to support specific data manipulation functions.” The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993)). “Nonfunctional descriptive material” includes, but is not limited to, music, literary works and a compilation or mere arrangement of data.

Both types of “descriptive material” are nonstatutory when claimed as descriptive material per se. Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive

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material, i.e., abstract ideas, stored in a computer-readable medium, in a computer, or on an electromagnetic carrier signal does not make it statutory. See *Diehr*, 450 U.S. at 185-86, 209 USPQ at 8 (noting that the claims for an algorithm in *Benson* were unpatentable as abstract ideas because “[t]he sole practical application of the algorithm was in connection with the programming of a general purpose computer.”) Such a result would exalt form over substance. In re *Saker*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978)...

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 7, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6, 7, and 11-15 recite at step (b), “calculating an occurrence frequency of each of the n unit sequences occurring on the genomic nucleotide sequence as a ratio of the number of each of the n unit sequences”. Applicant has not pointed to support in the specification for the “ratio of the number of each of the n unit sequences” for the “genomic nucleotide sequence” and none is apparent. Therefore, this is new matter.

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Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 15 recite “wherein said analytical oligonucleic acid is used as a primer”.

It is unclear if Applicant intends this to be an active method step or is this an intended use of the oligonucleic acid. Clarification is requested.

Conclusion

The outstanding rejections under 35 USC 112, 1st paragraph for lack of enablement have been withdrawn in view of Applicant’s amendments to the claims.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

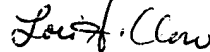
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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

May 7, 2006

Lori A. Clow, Ph.D.

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Patent Examiner